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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,821

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Haruo Sugiyama

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

02/21/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/541,821	Applicant(s) SUGIYAMA ET AL.	
	Examiner Sheela J. Huff	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 1 (in-part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 (in-part), 5, 6, 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed on 1/18/08 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Applicant has complied with the sequence rules.

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of applicant's amendments.

The rejection under 35 USC 101 is withdrawn in view of the cancellation of the claim.

The rejection under 35 U.S.C. 112, first paragraph, is withdrawn in view of the cancellation of the claims.

The rejection under 35 USC 103 is re-written in view of the amendments to the claims (see below).

Election/Restrictions

Newly submitted claim 1 (sequences 2-10, 12-17, 24-43 and 45-71) is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly added sequences were not originally presented and therefore were not examined in the first action. These added sequences are patentably distinct from the examined sequences (SEQ ID NO. 11, 18-23, 44 and 72) in that they are composed of a different composition and order of amino acid residues. Had all the sequences (SEQ ID NO. 2-72) been presented for examination prior to the first action, the sequences would have been subject to restriction.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 1 (SEQ ID No. 2-10, 12-17, 24-43 and 45-71) is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1 (in part), 5-6 and 11 are currently under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 (in-part), 5, 6 and 11 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over [EP 1103564 or EP 1371664 or Gaiger et al US 7063854 (filed 9/30/98)] in view of Di Modugno et al J. Immunotherapr vol. 20 p. 431 (1997).

Both of the EPs and the US patent disclose the peptide monomers as follows:

EP 1103564 discloses SEQ ID NO. 7 (see page 4, line 8) which reads on SEQ ID NO. 11 and 72 of the instant invention. This peptide is a product of Wilms' tumor suppressor gene WT1 and binds MHC class 1 and induces an immune response (see entire reference). Since these peptides induce an immune response they are use in a composition.

EP 1371664 discloses SEQ ID NO. 3 which reads on SEQ ID NO. 44 and 72 of the instant invention. This peptide is a product of Wilms' tumor suppressor gene WT1 and binds MHC class 1 and induces an immune response (see entire reference). Since these peptides induce an immune response they are use in a composition.

Gaiger et al discloses SEQ ID NO. 116 (col. 30), SEQ Id NO. 61 (col 44), SEQ ID NO. 144 (col. 46), SEQ Id No. 90, 55, 41 and 196 (col. 49-50) which reads on SEQ ID No. 11 and 72, 23, 20, 21, 18, 19 and 22 respectively. These peptides are HLA binding peptides and are derived from WT1 (see entire reference and tables in which each

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peptide is found) and induce an immune response. Since these peptides induce an immune response they are use in a composition.

The only difference between these references and the instant invention is the dimerization using a disulfide bond.

Di Modugno et al discloses the use of cysteines to form disulfide bonds in homodimers and that this increases the generation of different conformations which can lead to increased anti-tumor immune response (page 434-first column, last three paragraphs).

Thus, in view of Di Modugno et al which shows that dimerization using disulfide bonds can lead to increased anti-tumor immune response, it would have been obvious to one ordinary skill in the art to dimerize the monomers of the primary references and to use disulfide bonds in said dimerization with the expected benefits of increasing the immune response.

Response to applicant's arguments to the extent that they read on the above rejection

Applicant argues that the purpose of Di Modugno was to study whether ErbB-2 rich cysteine can form a dimer containing cysteines in vivo. This ErbB-2 was solely used as an example because as stated in the abstract and title of the reference the authors refers to peptides in general and makes statements such as "peptide derived from otherwise normal proteins, overexpressed in many tumors as products of the protooncogene, may represent a target for an immune response" (abstract).

Applicant argues that the Di Modugno reference does not examine CTL-inducing activity and that there was less HLA-A2 binding (and applicant refers to 48 dim and 789 dim). As seen in figure 2 there is increased binding in both 48 dim and 789 dim as compared to control. In view of this binding and in view of the fact that applicant's claims are product claims, it is expected (absent objective evidence to the contrary) that the homodimers of the reference can induce CTL activity.

Applicant also submits a declaration showing that the homodimers of a tumor antigen has CTL-inducing activity. While the declaration does show the CTL-inducing activity, it is not clear what applicant is trying with this declaration. If applicant is trying to show unexpected results, then the closest prior art should be compared with applicant's invention. However, no comparison is shown. If applicant is trying to show that the reference does not disclose CTL-inducing activity, as stated above, it is an expected property.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/

Primary Examiner, Art Unit 1643